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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,674	07/17/2003	Toby Freyman	10177-166-999	3657

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/622,674

Applicant(s)

FREYMAN, TOBY

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/5/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-63 and 65-69 is/are pending in the application.
- 4a) Of the above claim(s) 66-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-63, 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Applicant's amendment and response filed on October 5, 2006 have been received and entered into the case. Claims 1 – 49 and 64 are canceled; claims 66 – 69 are added; claims 50 – 63 and 65 – 69 are pending. Claims 66 – 69 are withdrawn from consideration and claims 50 – 63 and 65 have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 50 – 60 and 65 stand rejected under 35 U.S.C. 102(b) as being anticipated by Abatangelo.

Applicant claims a composition comprising decellularized bone marrow extracellular matrix, wherein the bone marrow extracellular matrix has been produced in vivo in an animal. The animal is a mammal selected from a cow, pig, horse, chicken, cat dog, rat, monkey or human; the human is an adult, adolescent, neonate or fetus; the extracellular matrix is arranged in a structure wherein the structure is maintained after the bone marrow is decellularized and the composition further comprises a biological material in the form of a scaffold, and is suitable for implantation.

Abatangelo teaches a biological material comprising extracellular bone marrow free of cellular components (or decellularized) and its use in tissue grafts (or are combined with biological materials) (abstract).

The reference does not teach the method by which the compositions are produced. However, these claims are considered to be product by process claims. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Applicant argues that the material of the claimed invention is structurally different than that disclosed in the art; and that the instant material is obtained from an animal, not culture.

However, these arguments fail to persuade because while applicant argues the structures are materially different, applicant has failed to disclose how the materials are structurally different. Specifically, applicant has neither disclosed how the structures of the materials are different nor provided any evidence supporting that the structures are materially different.

Regarding applicant's assertion that the instant material is derived from an animal not a culture, it is maintained that the patentability of a product does not depend on its method of production. Since applicant has not evidenced that the materials are in fact structurally different, the claimed product is the same or obvious from a product in the cited reference, even though the

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reference product was made by a different process. It is reiterated that when the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 50 – 63 and 65 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Abatangelo in view of Cobb.

Applicant claims a composition comprising decellularized bone marrow extracellular matrix, wherein the bone marrow extracellular matrix has been produced in vivo in an animal. The animal is a mammal selected from a cow, pig, horse, chicken, cat dogy, rat, monkey or human; the human is an adult, adolescent, neonate or fetus. The extracellular matrix is arranged in a structure wherein the structure is maintained after the bones marrow is decellularized; further comprises a biological material that is VEGF. Applicant claims a biocompatible material comprising decellularized bone marrow extracellular matrix wherein the bone marrow extracellular matrix has been produced in vivo in an animal, produced by a claimed method. The biocompatible material is a scaffold and is suitable for implantation into a patient.

Abatangelo teaches a biological material comprising extracellular bone marrow free of cellular components (or decellularized) and its use in tissue grafts (or are combined with biological materials) (abstract).

Abatangelo does not teach the composition further comprising VEGF. However, the reference does teach the composition for use in tissue grafts. At the time of the claimed invention, VEGF was known and used in the art with tissue grafts. In support, Cobb teaches tissue grafts in combination with VEGF (col.4). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine VEGF with the decellularized bone marrow of Abatangelo with a reasonable expectation for successfully obtaining the composition of Abatangelo.

The reference does not teach the method by which the compositions are produced. However, these claims are considered to be product by process claims. Thus, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Applicant argues that there is not motivation to combine the references; that the references address different technical problems; that there is no reasonable expectation for

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success; that the instant material is obtained from in vivo sources, not culture and that the examiner is using improper hindsight.

However, these arguments fail to persuade because Abatangelo specifically teaches that depending on the cells added to the bone marrow matrix, different growth factors are added (p.7-12). Thus, the reference suggests to one in the art that the specific growth factor added depends upon the cells (or biological material) added thereto. At the time of the claimed invention, one of ordinary skill in the art would have recognized that the matrix of Abatangelo could be used with any cell type for tissue grafts, and any corresponding growth factor. Since it was well known in the art that VEGF was commonly used in tissue grafts, it would have been obvious to one of ordinary skill in the art to use the cells and growth factors disclosed by Cobb in the material of Abatangelo with a reasonable expectation for successfully obtaining an effective biological matrix material.

Regarding applicant's assertion that the structures are materially different, applicant has failed to disclose how the materials are structurally different. Specifically, applicant has neither disclosed how the structures of the materials are different nor provided any evidence supporting that the structures are materially different.

Regarding applicant's assertion that the instant material is derived from an animal not a culture, it is maintained that the patentability of a product does not depend on its method of production. Since applicant has not evidenced that the materials are in fact structurally different, the claimed product is the same or obvious from a product in the cited reference, even though the reference product was made by a different process. It is reiterated that when the prior art discloses a product which reasonably appears to be identical with or slightly different than the

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claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper.

(MPEP 2113)

Finally, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Therefore, the claims stand rejected for these reasons and those made in the rejections above.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

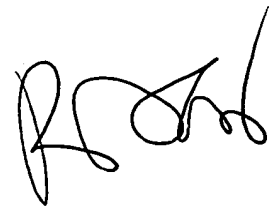
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis
Primary Examiner
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December 21, 2006